A STUDY TO DETERMINE AN EFFECTIVE ADMINISTRATIVE AND/OR ORGANIZATIONAL SYSTEM WITHIN WHICH TO IMPLEMENT EFFECTIVE QUALITY ASSURANCE FUNCTIONS OF THE PHARMACY AT LETTERMAN ARMY MEDICAL CENTER, THAT MEET JCAH AND HSC STANDARDS.

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This study was done to determine an effective administrative and/or organizational system within which to implement effective quality assurance functions of the pharmacy at Letterman Army Medical Center that meet Joint Commission on Accreditation of Hospitals and Health Service Command standards. The author concluded that a change in focus must be made, which concentrates on planned and systematic monitoring and evaluation of the quality and appropriateness of care, and away from administrative measures within the pharmacy.

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INTRODUCTION

Background Information

In July 1985, the Health Services Command (HSC) Annual General Inspection was conducted at Letterman Army Medical Center (LAMC) as part of their ongoing monitoring activities. One of the outcomes of the pharmacy review was a finding serious enough to require that corrective action be taken and documented. The finding encompassed the Quality Assurance (QA) program in the pharmacy and stated in part "The Pharmacy Service Quality Assurance program should be reevaluated...The program should be based on well-developed, preestablished, clinically valid criteria."[1] Additionally, this was noted to be a "repeat finding from the General Inspection, FY 1984."

In addition to this specific Inspector General Finding about the LAMC Pharmacy, there are indications that hospital pharmacy services throughout HSC have had difficulty implementing QA programs. As recently as January 30, 1986, the office of the HSC Inspector General published a list of comments and recommendations contained in a document titled Joint Commission on Accreditation of Hospitals (JCAH) Survey Reports conducted during 1985, in U.S. Army community hospitals. Two items of specific interest to pharmacy services are quoted.

> Information about pharmaceutical services is not routinely collected and periodically assessed for the purposes of identifying important problems in patient care services or for identifying opportunities to improve care.[2]

The quality and appropriateness of pharmaceutical services are not monitored and evaluated for all major clinical functions of the department/service.[3]

Difficulties in implementing the quality and appropriateness review aspects of hospital pharmacy QA programs is not unique to Army facilities. This belief is born out by the fact that the quality and appropriateness review portion of the pharmacy QA standard has been placed in an "implementation monitoring" status by the JCAH as of January 1986. In recognizing that this standard may require an extended period of time to implement, due to complex organizational issues, the JCAH has said that accreditation decisions will not be adversely affected due to lack of full implementation until July 1, 1987.[4]

While the problem itself may not be unique, there are additional factors which must be taken into account when viewing the LAMC pharmacy's QA program. The major factor is the philosophy that currently dominates the pharmacy service.

The Pharmacy Service within LAMC is currently preoccupied with the production aspects of service. This philosophy has been brought about most notably by the decreased manpower resources available in the pharmacy. Fewer people must perform the work previously accomplished by more. This dwindling manpower resource has in part been the cause of quality assurance system failures within the Pharmacy Service and has become visible throughout the facility. Because of the high cost of living within the San Francisco Bay Area and the inability of civil service to pay competitive wages for general schedule employees, there is a disparity between the salaries of government and private-sector pharmacy employees. The salary disparity is estimated at somewhere between $10,000 and $14,000. Vacancies for pharmacy personnel go unfilled for extended

periods of time, thus aggravating the limited personnel situation more. It is within this context that the LAMC pharmacy must conduct QA activities, and this is the reason this project was selected for review by the Deputy Commander for Administration.

Problem Statement

Determine an effective administrative and/or organizational system within which to implement effective quality assurance functions of the pharmacy at Letterman Army Medical Center that meet JCAH and HSC standards.

Objectives

1. Conduct a literature review in the areas of QA organization/ administration as they pertain to hospitals in general and pharmacies in specifics.
2. Evaluate the current QA organization/program in the LAMC Pharmacy to identify specific problem areas and strengths.
3. Request information from other DOD like size health care facilities to identify alternate, functional programs for pharmacy QA organization/administration.
4. Compare the DOD like-size facility QA programs against the current QA organization/administration at LAMC.
5. If necessary, develop a new QA administrative and/or organizational system.

Criteria

1. The QA system must have a planned and systematic method of monitoring the quality and appropriateness of services provided.
2. The QA system must have a systematic method of collecting information within the pharmacy and areas of concern.
3. The QA system must have a method for comparing clinically valid criteria against the information collected.
4. There must be an effective mechanism by which identified problems are resolved.
5. Problem identification and resolution must be documented, as does the ongoing monitoring process.

Assumptions

1. There will be no significant changes in requirements pertaining to pharmacy quality assurance, as specified in the JCAH Accreditation Manual for Hospitals.
2. The importance of quality assurance activities will not decrease.

Limitations

1. The proposed system shall require no additional manpower or funds.
2. In-depth interviews with pharmacy personnel of like-size DOD health care facilities can not be conducted due to time and distance limitations.
3. Recommendations of new system(s) will be subjective in nature due to non-quantifiable aspects of the study.

Research Methodology

The following research methodology will be utilized.

1. Literature review.

   a. Review literature that is generally applicable to the civilian health care industry.

   b. Review literature that is specifically applicable to DOD health care facilities (i.e., regulations, policies, statements, etc.)

2. Conduct interviews with the following offices in order to ascertain the specific nuances of the Army's Quality Assurance Program as it pertains to the pharmacy:

   a. Pharmacy Branch, Academy of Health Sciences.

   b. Inspector General, Health Services Command.

   c. Pharmacy Service, Brooke Army Medical Center.

   d. Pharmacy Service, Letterman Army Medical Center.

   e. JCAH Surveyor.

3. Request from other facilities a copy of their Pharmacy Quality Assurance Plan prior to 1 March 1986.

4. Evaluate the current Pharmacy QA System at LAMC.

   a. Examine documents used by the LAMC Pharmacy in order to gather information about the current QA system at Letterman Army Medical Center. This review should identify guidelines that are currently in place, the administrative organization that currently supports the QA program, and the standards that are currently used to measure QA performance.

   b. Observe how items of quality assurance interest are communicated (verbally and via documentation), integrated, and coordinated.

5. Review information that is gathered from like-size DOD facilities for the purpose of identifying a pharmacy quality assurance system that meets the above stated criteria. This determination will be based upon Inspector General and Joint Commission inspection reports. Review the documentation of facilities that meet the criteria to identify administrative and/or organizational systems that may be adaptable within the LAMC Pharmacy.
6. Recommend alternative systems. The recommendation will be based upon the information obtained via the literature review, interviews, and requests to other DOD facilities.

II. A HISTORICAL PERSPECTIVE

The issue of medical quality assurance has been with the medical profession for centuries. While this fact may come as a surprise to many health care professionals, the literature is replete with examples of early attempts to improve the quality of medical care. But it has only been in the relatively recent past, that quality assurance has begun to permeate the health care facilities and societal fabric of our nation. Organizations such as the Joint Commission on Accreditation of Hospitals have institutionalized the concept of quality assurance within our health care facilities, and persons dissatisfied with treatment received have brought their cases before the public in newspapers and court trials across the nation.

In this portion of the research study, I will trace the evolution of quality assurance from its early beginnings up to the recent revision of the quality assurance standard by the JCAH. I will then review the concept of departmental quality assurance in both its general terms and also in its specific applications within hospital pharmacy in Chapter III.

The Early Beginnings

Located in the Paris' Louvre is a seven-and-a-half-foot block of chiseled stone that attests to the earliest attempts to ensure quality care. The stone, dating from 2000 B.C., contains the cuneiform Code of Hammurabi, then the King of Babylon. It provides not only the first known listing of physician charges, but also penalties that were imposed upon providers if and when they displayed incompetent practice.[5]

> If a man's child has died under the care of a nurse, and the nurse has substituted another (nurse) without consent of his father and the mother, the breasts of that nurse shall be cut off.[6]
>
> If the doctor shall treat a gentleman and shall open an abscess with the knife and shall preserve the eye of the patient, he shall receive ten shekels of silver. If the patient is a slave his master shall pay two shekels of silver. If the doctor shall open an abscess with a blunt knife and shall kill the patient or shall destroy the sight of the eye, his hand shall be cut off.[7]

In ancient Egypt, papyri, approximately 4,000 years old, describe another important aspect of quality medicine: the need to set forth the state of the art so that others can practice it accordingly. By emphasizing and documenting quality medicine, information concerning the accepted method of treatment of various illnesses could be utilized by numerous practitioners throughout the land, thus setting a standard of practice that should be met.[8]

A number of centuries later (500 B.C.), the Greeks found themselves battling with the issue of quality care within their system. Aesculapius, who is credited with the founding of medical schools on the island of Cos, helped emplace a health care system in Greece, which was beneficial in teaching the healing profession of Hippocratic medicine. With its emphasis on prognosis, the placement of an accurate prognosis became the goal for all competent professionals to attain. Hence, while diagnosis was still important, the outcome of treatment received became of greater value.[9]

In the centuries that followed, countless examples of early efforts to define, standardize, and measure quality medical care are presented in the literature. To enumerate each of these efforts would be pointless except to say that they have met with varying degrees of success, and that these efforts have continued in spite of numerous obstacles. While the methods

have changed throughout history, these early examples provide evidence that the quality of medical care has been an issue for centuries. Our recent emphasis on QA is not a new issue, but a resurfacing of an old idea that has once again had emphasis placed upon it.

The Recent Past

In order to place the current QA standards in perspective it becomes necessary to review the work of two individuals--one from Britain, Florence Nightengale, and the other from the United States, Dr. Ernest A. Codman.

Florence Nightengale is considered by many to have been a critical link in the evolutionary process of modern day quality assurance. Her work during and following the Crimean War focused attention upon both the process and the outcome of care. She realized that the careful analysis of hospital and patient data could provide correlations between diagnostic category and mortality rates and between diagnostic category and specific medical and surgical treatments required. As a result of her efforts, she is credited with improving the quality of care rendered in British Army Hospitals and with developing a systematic method of reviewing the care provided.[10,11]

It was nearly half a century later before a surgeon at Massachusetts General Hospital by the name of Ernest A. Codman brought QA to the United States. Lamenting over the lack of outcome assessment in the United States he states:[12]

> "One might say that the instruction of the (medical) students is irrespective of the results to the patient, but let us suppose, in surgery, for example, that all the operations which have been watched

> by these students have been misdirected efforts at the cure of disease, and the students have learned to do something which is not worthwhile and does not really improve the patient. The product of the hospital in this case, even as regards student instruction, would be nil--even worse than nill. We are, therefore, referred again to the classification of disease and the results to the patients, because a student would naturally wish to receive his instruction at a hospital where the treatment was shown to be of benefit to the patient. We may then say that the product of the hospital in medical education, like the product in the number of cases treated, depends on whether or not the cases are well treated..."

Dr. Codman realized the need to be able to identify the outcomes of treatment, and in an effort to raise his own level of performance initiated a follow-up interview system on all patients on whom he had operated. From these retrospective studies he was able to determine whether his diagnosis was correct, whether the operation was a technical success, whether the patient had benefited from the operation, and whether or not the operation had produced some untoward effect.[13]

As a direct result of Dr. Codman's work, the American College of Surgeons, Hospital Standardization Program was created in 1918. For the next 33 years, this organization, the predecessor to the JCAH, would set minimal essential standards to which hospitals in the United States would attempt to comply.[14] Unfortunately, the lessons learned from Codman would be lost, and general standards replaced the more exacting end-result evaluations that he brought to the evaluation of medical care.[15] It would not be until 1966, when the JCAH rewrote its Standards for Hospital Accreditation, that a major change in philosophy would occur. In that year, the JCAH Board chose to guide hospital staff towards the provision of an optimal achievable, rather than the minimal essential, level of care that was set by the Hospital Standardization Program.[16]

As one can see, the interest in QA has been continuous throughout the years, but specific emphasis at different times has caused changes in the

methods that are used to measure the attainment of quality care. The current unrelenting emphasis placed upon QA is driven by many factors, but two events stand out as catalysts: Titles XVIII (Medicare) and Title XIX (Medicaid), and the increasing intolerance of the public towards inadequate quality in delivery of medical care.

The Influence of the Government

In 1965, the President of the United States signed into law Medicare/Medicaid legislation that has had an impact upon the delivery of health care to this date. The legislation did more than provide health services to millions of Americans; it also established a cooperative relationship between the government and the JCAH. In essence the legislation provided that hospitals that received accreditation from the JCAH would be deemed "in compliance with conditions of participation for Medicare/Medicaid eligibility."[17] Hence, accredited organizations would be eligible for federal funds under the program, and the JCAH gained a public sector legitimacy that it had not had previously. As public concerns over the quality of care increased, the JCAH would be looked towards as the organization to set quality standards.

To say that the impact of this legislation is significant would be a tremendous understatement. As cost became an increasing issue to the government as well as concerns about quality, the government again intervened and, the social security amendments of 1972 (P.L. 92-603) and 1975 (P.L. 94-182) were passed by Congress and signed into law. Their enactment created the now defunct Professional Standards Review Organizations (PSROs). The 203 PSROs were designed to involve health care

practitioners in the ongoing review and evaluation of health services covered by the Medicare/Medicaid legislation. Their mission was to evaluate the appropriateness of care provided, the necessity of that care, and its quality.[18]

As one can see by this brief review, it was during this time that the actions of the government began to have significant impact upon the delivery of quality health care. Monitoring of actions via the JCAH and the PSROs allowed the government to apply sanctions (withholding of funds) to those facilities that did not meet the required standards. If hospitals desired to remain financially solvent, the standards imposed by the newly legitimized JCAH would have to be met.

The Public Intolerance

Coincidentally, at the same time the Medicare/Medicaid legislation was being debated in the chambers of the nations capitol, another development was evolving that would catapult the issue of quality medical care to the forefront of public purview. The incident involved an individual named Dorrence K. Darling, who broke his leg while playing football in Charleston, Illinois. The subsequent malpractice lawsuit not only became a landmark decision but also marked the beginnings of virtually endless litigation involving the quality of care within hospitals throughout our nation. In rendering its decision, the Illinois Supreme Court held that JCAH regulations could be used as evidence "by custom" in a malpractice suit, thus lending further legitimacy to the JCAH and effectively establishing an expected level of medical care.[19,20,21]

Since Darling v. Charleston Community Memorial Hospital, the dramatic increase in malpractice premiums, which peaked during the malpractice crisis of 1974-1975, reflects the public awareness of this "expected level of care," and possibly the public intolerance of medical care that was perceived to be unsatisfactory. The public was no longer willing to accept care that they perceived as falling below this level; and more and more frequently they asked the courts to decide the issue.[22]

As more and more cases were brought before the courts and as the awarding of damages continued to grow, hospitals and providers began to feel pressured by the private sector. Hence, as both private and public sector actions continued to focus on the delivery of quality health care, hospitals became more aware of the necessity to conduct QA activities.

The Era of Audits

As pressure continued to mount, the JCAH continued to grapple with an effective method of ensuring quality of patient care in hospitals. In 1972, the JCAH published a Procedure For Retrospective Medical Care Audit. In 1973, the Procedure for Retrospective Patient Care Audit in Hospitals was published; and in 1974, the Performance Evaluation Procedure For Auditing and Improving Patient Care--also known as The PEP Primer--was published. The one thing that all these systems had in common was their reliance on audits. Because of this very fact, they all failed in the end, and the first concerted effort at a systematic QA monitoring program would have to be redesigned. The reasons for failure were many, but primarily, persons charged with the implementation of these audits became more concerned with the numbers of audits performed rather than the

quality of the care evaluated.[23] Physicians regarded the audits as tedious, costly, and time consuming, and efforts to meet audit requirements many times ended up as matters of paperwork compliance with a heavy emphasis being placed on data collection rather than on follow-up activities.[24] Because of these shortcomings, as well as survey findings and research that indicated patient care had not improved to the extend anticipated, a new and broadened approach to QA was undertaken by the JCAH in 1979. The focus was now to be on quality instead of on quantity.

The First Quality Assurance Standard

In April 1979, the JCAH adopted it's first "core" standard which focused solely on the provision of quality assurance. Its primary aim was to emphasize the need for a hospital-wide, problem-focused review that built on and integrated hospital activities. This action was then an attempt to integrate and coordinate diverse QA programs in a hospital, into a comprehensive QA effort.[25] The elements of the standard were written with the intent to allow flexibility in the implementation but at the same time to provide the guidance necessary to move in a new direction. These elements included:

- An integration or coordination of all quality assurance activities into a comprehensive program;
- a written plan for the program;
- a problem-focused approach;
- annual reassessment of the program; and
- measurable improvement in patient care or clinical performance.[26]

This standard was a radical departure from the previous audit-based attempts and represented the fruition of years of efforts to place QA as a centerpiece in hospital activities. The previous requirements for the conduct of a predetermined number of audits were eliminated, although the use of audits was not discouraged. Additionally, the use of a problem-focused approach implied that identified problems must be resolved in some sort of a prioritized manner. Finally, the review process would not be considered complete until corrective action was implemented and follow-up was initiated. The hospitals were left to determine the methods used for problem identification and resolution.[27]

It was under this standard that the seeds of departmental QA were sown. The standard did not mandate QA programs in each department or service, but the requirement for an integrated and coordinated program presupposed that efforts in the departments or services would be necessary. Since its publication in 1980, this standard has remained at the heart of the JCAH's drive for quality assurance, even though it underwent review in 1984.[28]

The 1984 Quality Assurance Standard

As with the old PEP audits, problems began to surface as to the effectiveness of the new QA standard. A survey conducted by the JCAH in 1982, showed that failure to meet QA standards accounted for the majority (61.6%) of contingency findings applied to hospital accreditation decisions. But more relevant to this paper is the fact that greater than one-third (36%) of all hospitals surveyed received recommendations suggesting less than full compliance with the QA standard in their

pharmacy's.[29] Although there appears to be many reasons why compliance was lacking (i.e., lack of corrective actions, and identification of problem that did not have an impact on patient care), the major concern voiced by the Commission was that the fundamental principle of quality assurance, ongoing, objective and systematic review, was not yet being fully implemented throughout the surveyed facilities.[30] The emphasis on a problem-focused approach resulted in the generation of lists of problems of which some were of no relevance to patient care. It was with this in mind that the JCAH refined the standard with the goal of emphasizing the importance of systematic quality review in each of the major QA requirements articulated in the standards. Thus, emphasis was placed not only upon systematic and ongoing monitoring but also upon quality assurance activities in departments and services. The major focus of each department's/service's QA effort would be the routine collection and periodic evaluation of information.[31] Because of the ongoing nature of this approach the need to conduct discrete studies in order to "locate a problem" should be eliminated. The required characteristics of the current standards as it pertains to the pharmacy require:[32]

- A planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care services and for resolving the identified problems;
- that the quality and appropriateness of patient care services are monitored and evaluated in all major clinical functions of the pharmaceutical service;
- that when problems or opportunities to improve patient care are identified, actions are taken, and the effectiveness of the actions is evaluated;

- that the findings and conclusions of monitoring, evaluation and problem solving activities are documented and reported, as appropriate;
- that actions taken and their impact are documented and, as appropriate, reported; and
- that the effectiveness of the monitoring, evaluation, and problem solving activities is annually evaluated.[32]

These same six points can be found in the quality assurance standard of 13 other hospital services that the JCAH surveys as well, and highlights the emphasis that is being placed on the conduct of QA activities at the departmental level. These new and refined standards, sometimes referred to as the "quality and appropriateness review standards," are the current standards that all hospital pharmacies must meet, including the Letterman Army Medical Center Pharmacy. Without a thorough knowledge of what the JCAH hopes to accomplish through this revision and how they measure implementation during survey, an evaluation of the LAMC program would be nonproductive.

FOOTNOTES

[1] Headquarters, United States Army Health Services Command Report of the General Inspection, FY 1985, Letterman Army Medical Center, California (July 1985): Finding 101 pp. 1-2.

[2] Headquarters, United States Army Health Services Command Recommendations and Comments From Joint Commission on Accreditation of Hospitals Survey Reports (30 January 1986): p. 13-1.

[3] Ibid., p. 13-2.

[4] Joint Commission on Accreditation of Hospitals (JCAH), "Accreditation Manual For Hospitals, Perspectives (January/February 1986): p. 3.

[5] Fine, David J.; Meyer Eve R., "Quality Assurance in Historical Perspective" Hospital and Health Services Administration (November/December 1983): p. 94.

[6] O'Brien, Robert M., "A Study to Determine the Best Way For Letterman Army Medical Center to Comply With the 1981 JCAH Quality Assurance Standard." Unpublished paper prepared at Letterman Army Medical Center, San Francisco, CA, 1980, p. 1.

[7] Fine, et al., p. 94.

[8] Ibid., p. 95.

[9] Ibid., p. 97.

[10] U.S. Defense Technical Information Center. "Quality Assurance Mechanisms in the United States: from there to where." Technical Report (October 1975): p. 3.

[11] "Ostrow, Patricia C., "The Historical Precedents For Quality Assurance in Health Care." The American Journal of Occupational Therapy (January 1983): p. 24.

[12] Codman, E.A., "The Product of a Hospital," Surgery Gynecology Obstetrics (April 1914): pp. 491-494.

[13] U.S. Defense Technical Information Center, Mechanisms, p. 5.

[14] Affeldt, John E., "Struggle For the Assurance of Appropriate Medical Care", Bulletin of the New York Academy of Medicine (January/February 1982): p. 41.

[15] Ostrow, Historical Precedents, p. 24.

[16] Affeldt, Struggle, p. 42.

[17] Ibid., p. 42.

[18] Lanham, Gary, "Quality Assurance in USA", World Hospitals (April 16, 1983): p. 60.

[19] O'Brien, Phillip J., "Emerging Malpractice Trends," Hospitals (April 16, 1983): p. 60.

[20] Graham, Nancy O., Quality Assurance in Hospitals (Rockville, Maryland: Aspen Systems Corporation), 1982: p. 7.

[21] Haffner, Alden D., Light, Donald W., Pena, Jesus J., and Rosen, Bernard, Hospital Quality Assurance (Rockville, Maryland: Aspen Systems Corporation, 1984): p. 26.

[22] Lamain, Marlene, Quality Assurance in Hospital Pharmacy (Rockville, Maryland: Aspen Systems Corporation, 1983): p. 156.

[23] Mattson, Marlin R., "Quality Assurance: A literature review of a changing field," Hospital and Community Psychiatry (June 1984): p. 607.

[24] Affeldt, John E., "The New Quality Assurance Standard of the Joint Commission on Accreditation of Hospitals," The Western Journal of Medicine (February 1982): p. 167.

[25] Affeldt, Struggle, p. 46.

[26] O'Brien, Letterman Army Medical Center, p. 6.

[27] Affeldt, New Quality Assurance Standard, p. 169.

[28] Ibid.,. p. 168.

[29] Roberts, James S., and Walczak, Regina M., "Toward Effective Quality Assurance: The evolution and current status of the JCAH QA standard", QRB (January 1984): p. 13.

[30] Ibid., p. 14.

[31] Ibid., p. 15.

[32] Joint Commission on Accreditation of Hospitals (JCAH) Accreditation Manual For Hospitals (Chicago: JCAH, 1985): p. 127-128.

III. QUALITY AND APPROPRIATENESS REVIEW

A survey of the quality assurance literature divulges a dearth of information in this area. The "newness" of the concept, coupled with its complex organizational implications, which have been alluded to earlier, have apparently caused a reticence to publish on the part of many authors. Fortunately, the authors that do address the issue provide tremendous insight into the intent and purpose of departmental QA. This portion of the research study will focus on the six characteristics of current quality assurance standards and their implications.

Planned and Systematic Monitoring

The first required characteristic calling for a "planned and systematic process for the monitoring and evaluation of the quality and appropriateness of care" stems from the JCAH's concern over the previous practice of sporadic, random identification of problems. This characteristic evolved in an effort to overcome the underdevelopment of monitoring systems found in most problem oriented programs.[1,2] By emphasizing a planned systematic process, the JCAH has stated that information collected should not be discrete in nature nor should it focus on individual problems that have come to recent attention. Instead, information gathering should be continuous in nature and reflect the results of day-to-day activities. In this way, trends and areas that may develop into problem areas can be identified prior to the actual occurrence of the problem.[3] Once information is

gathered, the characteristic goes on to say that there must be a planned and systematic process for "resolving identified problems." Once again, this concern represents a change of philosophy from the previous JCAH problem focused approach. Under the old approach, the department was required to follow a three step process of problem definition, problem analysis and action planning. Now, the department is left to its own devices, which may vary from costly indepth studies to inexpensive managerial actions. The only concern is that some action be taken to resolve the identified problem.[4]

If information must be gathered and the identified problems resolved, the question now becomes: What information should be monitored? The answer is spelled out in the standard with the phrase "the quality and appropriateness of patient care." By focusing on patient care, monitoring efforts must move away from administrative indicators of quality, and move more towards the actual delivery of a service to the patient. While administrative indicators (e.g. adequacy of reference library and updating of policies) are still important, they can not be allowed to become the focal point of a departments ongoing monitoring program. Day-to-day management and administrative functions should be reviewed as a routine function of the manager, separate and apart from those issues that directly impact upon the quality and appropriateness of care.[5] If that review uncovers QA issues, then they should be brought into the QA program, and monitored in the same way as other information.

Comprehensive and Criteria-Based

The second required characteristic states in part that "all major clinical functions of the department/service, shall be monitored, and that agreed upon...objective criteria that reflect current knowledge and clinical experience will be used in the monitoring and evaluation of patient care services." This characteristic is most important in pharmacy operations that are multidisciplinary and complex in nature. Pharmacies and phamacists no longer simply manage pharmacological products in isolation, but instead are responsible for participation in nutrition support teams, adjustment of dosage regimen and the provision of comprehensive drug information to other health care professionals.[6] As a result of this comprehensive monitoring a representative and adequate sampling of information should be obtained that gives the department manager an overview of all clinically oriented activities conducted under his area of responsibility and that covers the full scope of services provided. This monitoring should be conducted through the routine collection of information. No predetermined interval for the collection of information is provided in the characteristic, but the determination of such, much as the resolving of identified problems, is left for the department manager to decide. The intent is that an "ongoing surveillance system aimed at preventing and detecting problems will be instituted."[7] Anything less than this will be unacceptable.

As can be seen, the requirement for agreed upon objective criteria can also be found in this characteristic. This concept is not new, and in fact, it reentrenches the importance of objective criteria when evaluating collected information. These criteria, which must be agreed upon by the

appropriate department personnel, may take many forms. They may look at the structure (physical and organizational) of the department, the process of delivering care to the patient, or the outcome of the care provided. Additionally, the criteria may be normatively or empirically derived. The former is what the best informed experts say ought to be done or accomplished, and the latter is what is actually done or accomplished by a group or institution that one might wish to use as a standard for comparison. The list of methods in which criteria may be developed and classified--implicit versus explicit (JCAH prefers explict criteria), partly versus fully branched--goes on and on.[8] The important fact that must be realized by the department manager is that criteria must be present and be agreed upon by the knowledgeable personnel in the department. These criteria then act as screens to identify information for further evaluation, which does not meet the desired optimal level of performance of an event.

Action and Evaluation

The third characteristic states that when problems or opportunities to improve care are identified, actions are taken and the effectiveness of those actions are evaluated. Certainly, one of the main goals of any departmental QA program should be to create beneficial change aimed at improving the quality of services provided.[9,10] The requirement to take action and then evaluate the results provides the mechanism to affect this desired change. One fact that should be noted about this characteristic is that discovering problems is not required in order to meet the intent of the characteristic. The presence of a system thath will detect

problems or opportunities to improve care is all that is necessary. This then alleviates the necessity for the department manager to go problem hunting as has been done in the past. In fact, under this interpretation, it is now possible, although not probable, that a system structured to identify problems could meet the intent even though no problems were discovered during the process. However, once a problem is identified (as measured against the objective criteria), actions must be taken, and the problem reevaluated to ensure that the actions taken were sufficient to eliminate the problem. Failure to follow-up on actions taken would severely limit the ability of the manager to gauge whether or not the action was effective. Through this step, continued resolution of the problem is assured, and the loop from problem identification to problem resolution is closed.[11]

Documentation and Reporting

The fourth and fifth characteristics are treated as one entity in this discussion since both detail the necessity for documentation and reporting. Not only must the findings and conclusions of monitoring, evaluation, and problem-solving activities be documented and reported, but the actions taken and their impact on the problem must also be documented and reported as appropriate. While this work is the clerical portion of any QA program, it is the major method that the department manager has at his disposal to demonstrate compliance. In addition, it is the primary method that JCAH surveyors use to evaluate departmental compliance. As such, it becomes absolutely imperative that the steps taken in the QA effort be completely and accurately documented. This documentation must

go beyond the mere recording of findings, conclusions, and actions taken. Efforts should be made to record the types of monitors used and the criteria against which gathered information was compared. Additionally, the reasons why a specific action was taken and the specific outcomes of that action must be recorded. This goal can be accomplished by a permanent written record such as meeting minutes or special reports. If one fails to complete those tasks, the well planned and systematic program that the manager instituted may never be recognized for what it is. Instead, the program may become a statistic which is offered as an example to show the failure of this revised quality assurance standard, as others have been used in the past.[12]

The necessity to report the quality assurance effort is to insure that the facility has a well-integrated program. This is not to imply that every finding or action taken should be viewed as a problem that has facility wide implications, but rather as a mechanism to highlight those problems that are multidisciplinary or that require assistance from individuals or organizations beyond the confines of a single department. Unreported problems which require additional assistance in resolving, are destined to languish in the department without resolution ever occurring. Hence, a multitude of problems throughout the facility may never surfaced, and the combined efforts of the varied hospital resources never be applied. It is these very points that the JCAH is attempting to avoid by requiring a reporting mechanism in departmental QA programs.

Evaluation

Finally, the sixth characteristic requires that the effectiveness of the monitoring, evaluation, and problem-solving activities in the

department be evaluated annually. The department manager must view the QA effort as a living, dynamic program which will change with time. As such, items that are monitored this month may not be good items to monitor next month. Likewise, new programs and changes in services provided may require that new areas for information gathering be found. If an area that is monitored does not periodically identify a problem or opportunity to improve care, then it may be necessary to determine if the monitor is actually needed or possibly misdirected. While this characteristic requires that annual reevaluation take place, this process should be continuous, ongoing process, and formalized once a year. A program that requires major changes every twelve months without periodic readjustment during the interim months cannot be considered dynamic and responsive to the changing nature of health care. For this reason, the manager must keep abreast of the monitoring, evaluation, and problem-solving activities within the department. Failure to do so will result in a stagnant program which does not meet the intent of this characteristic, but, maybe even more importantly will cause the QA program to focus upon areas that are not relevant to quality assurance.[13]

FOOTNOTES

[1] JCAH, "Quality Assurance Standards Revised," Perspectives (May/June 1984): pp 1-3.

[2] Jessee, William F., "Quality Assurance Systems: Why Aren't There Any?" QRB (December 1984): p. 408.

[3] Academy of Health Sciences (AHS), "Quality and Appropriateness Review," Handout No. M 12-290-631-1-124 (1985): p. 2.

[4] Spath, Patricia, Cost Effective Quality Assurance, Portland, Oregon: Brown-Spath & Associates, (1984): p. 84.

[5] Evans, John, "How to Accomplish Quality Assurance in Pharmacy," (Unpublished report prepared at Brooke Army Medical Center, 1984): p. 1.

[6] Bradman, Douglas D., Russell, Wayne L., and Shaw, Marjorie A., "Quality Assurance in a Clinical Pharmacy Program," QRB (March 1984): p. 87.

[7] AHS, Quality and Appropriateness, p. 6.

[8] Donadedian, Avedis, "Criteria and Standards For Quality Assessment and Monitoring," QRB, (March 1986): pp. 99-108.

[9] Crane, Vicki S., "Quality Assurance as a Problem-solving Technique," Health Care Supervisor (October 1984): p. 59.

[10] Burkle, Wayne S., "Developing a Quality Assurance Program for Clinical Services," Hospital Pharmacy, (March 1982): p. 127.

[11] AHS, Quality and Appropriateness, p. 12.

[12] Spath, Cost Effective, p. 107.

[13] AHS, Quality and Appropriateness, p. 14.

IV. DISCUSSION

Army Regulation (AR) Number 40-2, Army Medical Treatment Facilities General Administration, states that it is the objective that all eligible U.S. Army hospitals be accredited by the Joint Comission on Accreditation of Hospitals. Based upon this requirement, the Army hospitals strive to meet the standards presented in the Accreditation Manual For Hospitals (AMH) as they pertain to quality assurance. It is within this same Army Regulation that the requirement for general administration in Army pharmacy's is located. A review of this regulation and of bulletins, provided by the pharmacy consultant to the U.S. Army Surgeon General, reveal no additional QA requirements at the current time, although a revision of the regulation is in the offing and should address QA in more detail as it pertains to hospital pharmacy. Because of the lack of additional requirements, the LAMC pharmacy QA program is evaluated against the JCAH standard, which is in essence the Department of the Army standard as specified in AR 40-2.

The review and evaluation of the Pharmacy QA program was conducted over a period of nine months and included participation in the pharmacy department's QA meetings, the medical center's QA meetings, and the medical center Therapeutic Agents Board. Additionally, the minutes of each of these meetings were reviewed in order to determine the amount and type of documentation and reporting that was being done. The pharmacy QA plan was reviewed as was a number of other documents (e.g., LAMC pharmacy newsletters, LAMC pharmacy notes, and the Surgeon General's pharmacy consultant's bulletin). Finally, conversations were held with persons

employed in the LAMC pharmacy and with other persons knowledgeable in the operation of an Army pharmacy and familiar with JCAH Accreditation Standards. Most notable among these individuals were LTC(Ret) Glidden N. Libby, former HSC Inspector General, LTC Richard Ihlenfeld, Chief, LAMC Pharmacy, LTC Richard J. Ferrell, Instructor, U.S. Army Academy of Health Sciences, MAJ Allen D. Whisenant, former Pharmacy QA Coordinator, Brooke Army Medical Center and Ms. Cornelia Cassidy, JCAH surveyor.

General Conclusion

The Letterman Army Medical Center Pharmacy does have a functioning quality assurance Program, which is administered and organized under the chief pharmacist. The scope and focus of the QA program has changed over the last nine months, but deficiencies still remain that must be corrected in order to meet the six characteristics of the pharmacy QA standard.

In general, a change in focus must be made, which concentrates on planned and systematic monitoring and evaluation of the quality and appropriateness of care, and away from administrative measures within the pharmacy. Additionally, increased efforts must be made towards the reevaluation of problems and the effectiveness of actions taken along with a more complete documentation of the program.

Planned and Systematic Monitoring

The pharmacy quality assurance program, as it is currently administered, involves the monitoring and reporting of 73 different "Topics For Evaluation" at various times throughout the year. In this

way, each of the 73 topics will be discussed at the monthly departmental QA meeting at least once each year. Some topics such as reports of unusual occurrences and reports of adverse drug reactions are reviewed on a monthly basis.

A review of the minutes shows that, as a result of these monitoring activities, a number of problems have been identified. Unfortunately, of the 21 different items that have been placed on the pharmacy's "problem solving log," greater than 70% have focused upon administrative issues such as physical security, staffing, budget, and inspection visits. The information that was occassionally gathered on the quality and appropriateness of care generally surfaced through unusual occurrence reports (18 times) or adverse drug reaction reports (three times). Both types of reports are normally generated only after the patient becomes directly involved in the problem. The majority of these incidents were dismissed as one time occurrences and not deemed important enough to be followed up according to the minutes. Thus, it can concluded that the pharmacy's efforts are apparently misdirected towards the monitoring of administrative problems, rather than the quality and appropriateness of care.

Additionally, it should be noted that the current "schedule" in which topics are evaluated in the QA program discourages the monitoring of day-to-day activities in a planned and systematic manner. Instead, persons are encouraged to monitor and gather information about certain activities on a predetermined basis with long intervals between monitorings. Such items as "review/audit drug utilization (DUR) and antibiotic usage (AUR)" are scheduled for monitoring every other month or "as needed." While this process may be acceptable in theory, in practice only one series of DURs or AURs has been completed in the last nine

months. Although this process has been exacerbated by personnel shortages and is a multidisciplinary problem, it is one of the major areas that the quality and appropriateness of care can be affected. This type of scheduled monitoring, accompanied by an inability to complete the monitoring activities, does not meet the intent of an ongoing surveillance system aimed at preventing and detecting problems.

Comprehensive and Criteria-Based

As has already been noted in the preceding paragraph, drug utilization review and antibiotic usage review is not being frequently performed within LAMC. This fact is deliberately pointed out as a facility problem because of the multidisciplinary nature of the problem and as an example of the lack of comprehensiveness in the information gathering and monitoring system. Even though this is a function of the medical staff as outlined in the AMH, the pharmacy has a responsibility to participate in the process of conducting the reviews and is held partially accountable if the process is not completed. Without this function being accomplished, the pharmacy program can not be considered as a totally comprehensive one.

In order to further discuss the comprehensiveness of the information gathering and monitoring system, it becomes necessary to review the structural organization of the pharmacy. As an organization, the pharmacy is comprised of a number of sub-elements. Among these elements are the:

- sterile products section,
- unit dose section,
- radiopharmacy section,
- hematology/oncology section, and
- outpatient section.

In the pharmacy QA plan, each of these elements is identified, and a representative of each section is designated as a member of the monthly departmental QA committee. This structural alignment should encourage a comprehensive review of information that has been gathered throughout the preceding month. Attendance at QA meetings and review of the minutes does not show this fact to be the case, however. Most notably missing are contributions by the members of the radiopharmacy. Of the 18 unusual occurrence reports generated in the past nine months, only one has been reported in the radiopharmacy section. While this in itself cannot be pointed to as an indicator of comprehensiveness, it should be noted that discussion and/or participation by members of the radiopharmacy section, during QA meetings is minimal and seldom recorded in the minutes. This example can be viewed as an instance where the comprehensiveness of the pharmacy QA program could be further expanded, specifically into this clinical pharmacy area.

Additionally, assessment criteria have been devised for each section of the pharmacy, although not all criteria measure the quality and appropriateness of care. Examples of such criteria are ones requiring rotation of shelf stock in the hematology/oncology section and also in the sterile products section. Criteria such as these may be good managerial tools but do not necessarily belong in the QA program.

Action and Evaluation

Review of the pharmacy QA program does in fact show that once information is gathered and problems (albeit mostly administrative) are identified, the action taken is directed towards the ultimate resolution of the problem. Routinely what occurs is that a knowledgeable individual

within the pharmacy is identified as responsible for seeing that appropriate steps are taken and actions continue until problem resolution is reached. This approach is certainly acceptable under the third characteristic. The range of actions taken is large and varies from simple administrative adjustments to extensive efforts to educate the medical staff members to the importance of DUR and AUR. Additionally, when gathered information clearly shows that mistakes are traceable to a specific individual or individuals, efforts are made at maintaining the professional competency of pharmacy employees through an inservice education program and through individual educational counseling sessions.

Although actions do appear to be taken, there is not a mechanism that keys the reevaluation of the problem nor the effectiveness of the action taken after resolution is reached. Once a problem is resolved, it is dropped from the problem solving log and not reevaluated unless it again becomes a problem.

Documentation and Reporting

As has been noted throughout this discussion, there are methods in the QA program that are used to document findings, conclusions, and actions taken. Most notable of these methods are the recording of the QA minutes and the annotations that are made in the accompanying problem-solving log and the problem-status summary. Likewise, the structure, along with the criteria that are used during the monitoring process, are found in the QA plan.

It is largely because of these documents that this study has been completed. Also as a result of this documentation omissions in the program have become identifiable. The major omission that has been

identified is the lack of documentation in the minutes of the criteria against which gathered information is measured. Criteria are in fact used in the pharmacy as has been previously noted, but the lack of documentation in the minutes and accompanying logs gives the appearance that the criteria are not utilized nor present in the program. Thus the documenting of where and how the criteria are used is an important omission that should be corrected.

The method in which problems or opportunities to improve care are reported, as appropriate, is accomplished via monthly review of the departmental QA minutes by the facility QA committee. An analysis shows that over the last nine months, less than 50% of the pharmacy QA minutes have been formally reviewed by the committee. However this number is in some ways a deceptive statistic since the chief of the pharmacy is represented on the hospital QA committee and gives input of appropriate information for the committees consideration. If anything, this example points out a hospital QA problem, in which information that is recorded and dispatched in a timely manner is not formally included for review and integration by the hospital QA committee.

Evaluation

The JCAH requires that evaluation of the effectiveness of the monitoring, evaluation, and problem-solving activities in the department takes place annually. Since the initiation of this study, one complete revision of the program has taken place and another evaluation is being initiated. The pharmacy thus meets this requirement in its entirety.

The Other Plans

It would be redundant and presumptious to attempt to offer specific steps that should be taken in order to correct the deficiencies identified. In that the conduct of pharmacy quality assurance activities is in a large part common sense, built within a framework of pharmacological knowledge, the deficiencies noted can be resolved by a thorough understanding of the quality and appropriateness standard, a redirection away from the administrative indicators, of quality care, increased attention on program comprehensiveness, and a more complete documentation of criteria and follow-up activities.

Because these types of activities represent a requirement to change the focus of the program, and because the literature has shown that difficulties have been encountered by hospital pharmacies attempting to meet this new requirement and its predecessor requirement, the additional step of reviewing the pharmacy QA programs of DOD likesize facilities was undertaken. The intent was to compare these programs against the LAMC pharmacy program and to glean appropriate ideas from them that should assist in refocusing the LAMC program if necessary. As a result, the pharmacy QA plans were requested and received from Fitzsimmons Army Medical Center (FAMC), Aurora, Colorado; Womack Army Community Hospital (WACH), Ft. Bragg, North Carolina; Brooke Army Medical Center (BAMC), Ft. Sam Houston, Texas, and Bethesda Naval Medical Center (BNRMC), Bethesda, Maryland.

The first two plans that were reviewed against the JCAH standards were from FAMC and WACH. Upon initial inspection, it became apparent that these two plans and the one from LAMC were copied from one another.

Because of this, the focus of the three programs apparently is the same, although differences in the process used to carry out the plan may slightly differ. This similarity excludes either program from serving as an alternate functional program as originally anticipated in this study's objectives.

The next plan that was reviewed was the one from BNRMC. Inspection of their QA plan revealed a program which was problem oriented and geared toward the philosophy of the 1981 Quality Assurance Standard. It is for this reason that this program was excluded from serving as an alternate functional program as originally anticipated in the objective.

The final plan that was reviewed came from BAMC, and is appropriately titled the "Quality Review Program." The purpose of the program as stated is to "define the committee structure and procedures to systematically monitor and evaluate the quality and appropriateness of pharmaceutical services provided by all pharmacy service sections." The program requires the development of a Quality Review Committee that is responsible for the oversight of the pharmacy program and for evaluating the program's effectiveness. Additionally, supervisors in each pharmacy section are responsible for the development of indicators that reflect the degree of quality and appropriateness of patient care provided, development of data collection instruments, criteria, and the day-to-day monitoring of the selected indicators. In this way, the individuals who are most knowledgeable devise the methods of gathering and evaluating information. As a result of these actions, written summaries of problems or improvement opportunities are forwarded to the quality review committee for review of actions taken and review of the effectiveness of those actions. Finally, the quality review committee acts as the mechanism for

the appropriate reporting of problems and improvement opportunities to the hospital QA committee. In this way, the pharmacy program is integrated with the facility program.

In addition to these requirements, the BAMC program also integrates the risk management and utilization review program into one document, something that the LAMC pharmacy program omits. In this way, three of the four activities encompassed in a comprehensive QA program are covered under a single umbrella. The fourth activity, credentialling, is omitted due to its administrative nature, but is accomplished as required.

It is for these reasons that the BAMC program is seen as a good program that adheres to the intent of the 1984 pharmacy QA standards that the LAMC pharmacy should pattern itself after. Although any such adaptation must be approached with a degree of caution, since no two pharmacies are identical and organizational relationships may vary in some aspects. Given these considerations and careful planning, the LAMC program should be able to redirect its focus and preclude future findings by external monitoring organizations.

V. SUMMARY

The intent of this study has been to determine an administrative and/or organizational system within which to implement effective quality assurance functions of the pharmacy at Letterman Army Medical Center, which will meet JCAH and HSC standards. During the course of this study, it has been shown, that the concept of quality assurance is not a new idea but rather an idea that has periodically surfaced and prevailed throughout recorded history.

The current emphasis that is being placed upon QA is based upon a multiplicity of factors, which include: governmental involvement in the health care system, increased public awareness, and increased litigation concerning the level of care provided. As a result, standards set by the Joint Commission on Accreditation of Hospitals became the mechanism that was used to determine if a predetermined expected level of care was being provided. Through a series of revisions, these standards still remain the guiding force that drives hospitals towards providing departmental QA, and more specifically that requires hospital pharmacies to establish and execute quality assurance activities aimed at a planned and systematic process for monitoring and evaluating the quality and appropriateness of care.

The LAMC pharmacy QA program was measured against this standard. Although this study did discover an effective administrative and organizational system in which to implement effective quality assurance functions in the pharmacy, significant discrepancies with the 1984 standard were discovered. Primary among these were the misdirection of focus towards administrative problems instead of at the quality and

appropriateness of care and a lack of consistent reevaluation of problems and the effectiveness of actions taken. Additionally, the program was not found to be as comprehensive as necessary and that critical items such as the type of criteria used, against which gathered information is measured, were not fully documented.

It was concluded that it was not advisable to provide step-by-step corrective actions, but to attempt to locate and identify an alternate functional program that could be drawn upon to improve the LAMC pharmacy QA program. Of the four pharmacy department QA plans that were requested and received, only one appeared to focus upon a planned and systematic process for the monitoring and evaluating of the quality and appropriateness of care; this plan came from Brooke Army Medical Center.

Consequently, the BAMC plan was identified as the one plan that would most likely be adaptable to the LAMC pharmacy, although two areas of caution were pointed out. First, no two pharmacies are identical and changes in the BAMC plan may have to be made if adaptation is to be successful. Second, organizational relationships in the two organizations must be taken into account when adapting the BAMC plan to LAMC. Finally, if the BAMC plan is implemented and the program's focus redirected, further negative findings by external monitoring organizations should be minimal as they relate to quality assurance.

APPENDIX A

DEFINITIONS

DEFINITIONS

Health Services Command - A major Army command that is responsible for providing health services for the Army in the continental United States, Canal Zone, Alaska, Hawaii, Johnston Island, Guam and Trust Territory of the Pacific Islands.

Inspector General - An Army staff element which has the responsibility to determine the state of economy, efficiency, discipline, morale, esprit de corps, and readiness throughout the Army.

LAMC Pharmacy Newsletter - Newsletter published for the purpose of disseminating information to the clinical staff of the medical center.

LAMC Pharmacy Notes - Newsletter published for the purpose of disseminating information to patients of the medical center.

Problem Solving Log - A pharmacy quality assurance document which allows for the recording of identified problems, frequency of monitoring activities, responsible individual, requirement measured against, action taken, result of completed action, and mechanism for sustained monitoring.

Problem Status Summary - A pharmacy quality assurance document that allows for the recording of identified problems, date of identification of problem, completion date of actions taken and remarks.

Therapeutic Agents Board - Committee whose purpose is to recommend the adoption or assist in the formulation of broad professional policies regarding the evaluation, selection, procurement, distribution, use, safe practices, and other matters pertinent to drugs in Letterman Army Medical Center.

Topics for Evaluation - A listing of 73 clinical and administrative items which are checked by the pharmacy, at least one per year, and the results incorporated into the pharmacy quality assurance program.

U.S. Army Surgeon General - The individual responsible for development, policy direction, organization, and overall management of an integrated Army-wide health services system.

APPENDIX B

BROOKE ARMY MEDICAL CENTER QA PLAN

DEPARTMENT OF THE ARMY
BROOK ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234

HSHE-PH
SOP #33

8 October 1985

QUALITY REVIEW PROGRAM

1. Purpose: to define the committee structure and procedures to systematically monitor and evaluate the quality and appropriateness of pharmaceutical services provided by all Pharmacy Service sections. This procedure includes guidance for Quality Assurance, Risk Management, Utilization Review, and Regulatory Requirements Review.

2. Quality Review Committee:

a. Membership:

Chief, Pharmacy Service, Chairperson

Assistant Chief, Pharmacy Service, Member

NCOIC, Pharmacy Service, Member

Supervisor, Clinical Pharmacy Section, Member

Supervisor, Inpatient Pharmacy Section, Member

Supervisor, Outpatient Pharmacy Section, Member

Supervisor, Pharmacy Support Section, Member

Resident, Pharmacy Service, Recorder

b. Meeting Frequency: Monthly

c. Functions and Responsibilities:

(1) To develop, monitor, and evaluate quality assurance, risk management, and utilization review programs for all sections of the Pharmacy Service.

(2) To insure that all pharmacy sections are in compliance with Army regulatory requirements and published professional standards for pharmacy.

(3) To implement corrective action and then evaluate the effectiveness of the corrective actions when problems or opportunities for improving services are identified.

Supersedes HSHE-PH SOP #33, 20 January 1982

d. A record of business transacted at monthly meetings will be maintained in the format of official meeting minutes and forwarded to the medical center's Quality Assurance Committee for review.

3. Quality Assurance Program:

a. Purpose: To monitor and evaluate in a planned and systematic manner critical indicators of quality of care for each section of the Pharmacy Service to determine the adequacy and appropriateness of services provided and to correct identified problems.

b. Responsibilities:

(1) Quality Review Committee:

(a) Reviews indicators and data collection techniques and determines their validity based on the expert opinion of the committee.

(b) Reviews summary of data collected, trend analysis, and recommendations for corrective actions made by section supervisors.

(c) Implements corrective actions when problems or opportunities for improving the quality of pharmaceutical services provided are identified.

(d) Evaluates the effectiveness of corrective actions taken.

(2) Supervisors of Clinical, Inpatient, Outpatient, and Support Sections:

(a) Select indicators which focus on the most critical functions of each section that impact on the quality and appropriateness of patient care. The indicators selected must be measurable and allow for efficient collection of data without disruption of the sections routine work flow.

(b) Develop data collection instruments for each indicator.

(c) Monitor each indicator as a part of the day to day routine of the section. Staff members should be included in the data collection process.

(d) Provide a written summary of data collected and a trend analysis to the Quality Review Committee quarterly. This will include a statement of problems or opportunities for improvement identified and recommended actions to be taken. The Inpatient Section's report will be submitted the first month of each quarter; Outpatient Section's the second; and Clinical and Support Sections' the third.

(e) Indicators and data collection instruments developed by the Clinical, Inpatient, Outpatient, and Support Section supervisors will be added to this SOP at appendixes A, B, C, and D respectively. For each indicator, the supervisor will identify the section and function being

evaluated, state the indicator, and define the data collection procedure; the format is at Appendix E.

(3) Staff members:

(a) Accomplish the required monitoring efficiently and accurately.

(b) Report any occurrence that impacts on the quality of care that the patient receives.

4. Risk Management Program:

a. Purpose: To prevent and/or limit harm to a patient that results from errors made by pharmacy staff members during the completion of daily work.

b. Responsibilities:

(1) All staff members: Immediately report all errors to the supervising pharmacist and prepare a written report of the incident utilizing the Pharmacy Service Incident Report form. The report should identify the patient and answer the questions of who, what, when, and where; corrective actions taken must be documented.

(2) Supervising pharmacist:

(a) Take whatever steps are necessary to limit and/or prevent further harm to the patient when an error is detected.

(b) Notify the Chief of Pharmacy Service of the incident as soon as possible.

(c) Review the incident report form for completeness, sign and date, and forward to the Chief of Pharmacy Service.

(3) Quality Review Committee:

(a) Review all Pharmacy Service incident reports; professional competency of individuals involved will be assessed.

(b) Review all patient complaints.

(c) Review all drug recall notices

(d) Review all pharmaceutical medical material complaints.

(e) Initiate corrective action when problems or opportunities for improvement of services provided are identified.

(f) Evaluate effectiveness of corrective actions taken.

5. Utilization Review Program:

a. Purpose: To assure appropriate allocation and utilization of

available resources in an endeavor to provide high quality patient care in the most cost efficient manner possible. This program addresses over utilization, under utilization, and inefficient use of resources.

b. Review schedule is at Appendix F.

c. Responsibilities:

(1) Quality Review Committee: Review reports of utilization review and take corrective action when indicated.

(2) Assistant Chief: Review manpower authorizations

(3) Supervisor, Clinical Section:

(a) Review antidote availability

(b) Review adequacy of reference library

(3) Supervisor, Inpatient Section:

(a) Review Ward Drug Storage Inspections

(b) Review list of bulk drugs authorized to issue to unit dose wards.

(4) Supervisor, Outpatient Section: Review clinic drug storage inspections.

(5) Supervisor, Support Section:

(a) Review expenditures for previous month and year to date.

(b) Review the high cost line items.

(c) Review all drugs with no usage during previous six months.

(d) Review adequacy of equipment for all pharmacy sections.

(6) NCOIC:

(a) Review productivity for previous month; UCA units/man hour for each work area.

(b) Review technician task list.

6. Regulatory Requirements Review Program:

a. Purpose: To establish procedures for the systematic review of Pharmacy Service SOPs and compliance with requirements of Army regulations and recommendations of JCAH.

b. Responsibilities:

(1) Quality Review Committee will review adequacy of compliance with all requirements and take corrective action when required.

(2) Assistant Chief will review all administrative policies and those that affect more than one functional area of the pharmacy and submit recommendations for changes to the Quality Review Committee.

(3) The supervisors for Clinical, Inpatient, Outpatient, and Support Sections will review policies and procedures for their respective sections and submit recommendations for changes to the Quality Review Committee.

c. Review schedule is at Appendix G.

LINN J. DANIELSKI
LTC, MS
Chief, Pharmacy Service

QUALITY ASSURANCE
PHARMACY SERVICE
BROOKE ARMY MEDICAL CENTER

PHARMACY SECTION: (Section to be evaluated)

1. INDICATOR: (Description of procedure or event to be evaluated.)

2. ASSESSMENT: (Methodology for evaluation of compliance with indicator. Include instructions for completion of data collection instrument)

3. CORRECTIVE ACTION: (Immediate corrective actions to be taken a problem is found during the evaluation process.)

4. EVALUATION: (Procedures to be used to evaluate collected information.)

OUTPATIENT PRESCRIPTIONS

OUT OF STOCK
INCORRECTLY TYPED
INCORRECTLY FILLED
INCORRECTLY DISPENSED
ADVERSE DRUG REACTIONS
DRUG INCOMPATIBILITIES

INPATIENT CARE

STERILE PRODUCTS

INCORRECTLY LABELED
INCORRECTLY MANUFACTURED
MISSING DOSE
CONTAMINATION
ADVERSE DRUG REACTIONS
DRUG INCOMPATIBILITIES

UNIT DOSE

MISSING DOSE
WRONG STRENGTH
WRONG DRUG
STAT ORDER RESPONSE
ADVERSE DRUG REACTIONS
DRUG INCOMPATIBILITIES

SUPPORT SECTION

SUPPLY

DUE OUTS
ZERO BALANCES
SPECIAL ORDERS

QUALITY CONTROL

RECALLS
OUTDATED ON SHELF

MANUFACTURING

INCORRECTLY LABELED
INCORRECT INGREDIENTS
BATCH NOT RELEASED

CLINICAL PHARMACY

NUCLEAR

MOLY BREAKTHROUGH
PERCENT TAGGING
PATIENT DOSE
INCORRECTLY LABELED
INCORRECTLY MANUFACTURED
MISSING DOSE
ADVERSE DRUG REACTIONS
DRUG INCOMPATIBILITIES

HEMATOLOGY/ONCOLOGY

INVESTIGATIONAL DRUGS
DRUG MONITORING
INCORRECTLY LABELED
INCORRECTLY MANUFACTURED
MISSING DOSE
ADVERSE DRUG REACTIONS
DRUG INCOMPATIBILITIES

PHARMACY SERVICE
UNUSUAL OCCURRENCE REPORT

Analysis of incident: Report Date:_____

Dosage Form:
__ IV infusion
__ TPN
__ IV Push
__ IVPB
__ Syringe
__ Oral tablet
__ Oral capsule
__ Suppository
__ Cream/Oint
__ Otic
__ Ophthalmic

Medication Incident:
__ Missing dose
__ Unordered drug
__ IV fluid
__ IV volume
__ Concentration
__ Dose
__ Labeling
__ Directions for use
__ Administration rate
__ Administration time
__ Wrong drug

Individuals Involved:
__ Physician
__ Pharmacist
__ Pharmacy Technician
__ Pharmacy Student
__ Pharmacy Reservist
__ Nurse
__ LPN
__ Corpsman
__ Other: _____

Cause of Incident:
__ Order interpretation
__ Profile transcription
__ Drug selection
__ Order not received
__ Indication for use
__ Computer input

Medications Involved:

CLASS OF OCCURRENCE: (Physician must be notified if Class I occurrence)

__ I: Dispensing error; patient took incorrect medication or dose.
Physician:_____ date/time:_____
Physician's comments:

__ II: Dispensing error; issued to patient or ward but not administered.
__ III: Procedural problem detected prior to dispensing.

Action taken by pharmacy personnel:

Patient Name: _____ Phone: _____
Address/Ward: _____
Time/date error occurred:_____ Rx/IV number:_____
Place error occurred:_____
Time/date error detected:_____
Place error detected:_____

Reviewed by:	signature	date
Section chief:	_____	_____
Chief Pharmacy Svc:	_____	_____
QA Committee:	_____	_____

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